



#### Cleveland Clinic Laboratories

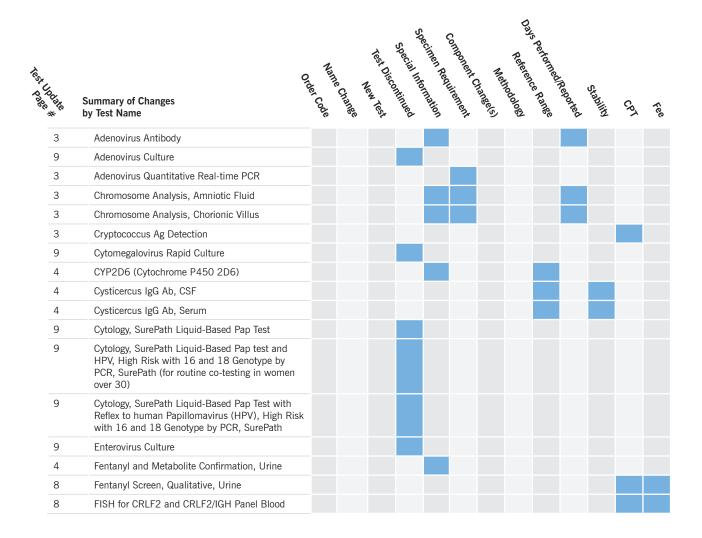
#### Technical Update • November 2022

Cleveland Clinic Laboratories is dedicated to keeping you updated and informed about recent testing changes. This Technical Update is provided on a monthly basis to notify you of any changes to the tests in our catalog.

Recently changed tests are bolded, and they could include revisions to methodology, reference range, days performed, or CPT code. Deleted tests and new tests are listed separately. For your convenience, tests are listed alphabetically and order codes are provided.

To compare the new information with previous test information, refer to the online Test Directory at clevelandcliniclabs. com. Test information is updated in the online Test Directory on the Effective Date stated in the Technical Update. Please update your database as necessary.

For additional detail, contact Client Services at 216.444.5755 or 800.628.6816, or via email at clientservices@ccf.org.



# Test Dadate

### Summary of Changes by Test Name

# Days Performed Reported Reference Rames Speciment Requirement Component Chames(s) Hotomation Speciment Requirement Lest Discontinued Lest Discontinued Order Code Order Code

8	FISH for CRLF2 and CRLF2/IGH Panel Bone Marrow							
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9	Leishmaniasis Antibody IFA							
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9	Paroxetine							
6	PML/RARA RTPCR							
7	Sertraline							
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7	T4							
7	Trazodone							
9	Trypsin							
7	Venlafaxine & Metabolite							

## Test Changes

Test Name	Order Code	Change	Effective Date
Adenovirus Antibody	SADNAB	Special Information: Patient preparation: Fasting. Grossly hemolyzed, lipemic or icteric specimens will be rejected.  Days Performed: Tue–Sat Reported: 3–6 days	12/13/22
Adenovirus Quantitative Real- time PCR	ADVQNT	<b>Specimen Requirement:</b> 2 mL plasma from EDTA (Lavender) tube; Frozen; Do not use gel separator tubes. Transfer plasma to standard aliquot tube. <b>Note:</b> ACD A or B (Yellow) and No additive (Red) tubes are no longer alternate specimen types	effective immediately
Chromosome Analysis, Amniotic Fluid	FAMCYT	Includes: Specimen Type Cells Counted Colonies Cells Analyzed Cells Karyotyped GTG Band Resolution Achieved Cytogenetic Diagnosis Cytogenetic Diagnosis Cytogenetic Interpretation Director Review Special Information: Discard first 2 mL of amniotic fluid. Collect specimen in two screw top plastic tubes. Do not centrifuge. Specimens found not to be amniotic fluid, grossly contaminated with blood cells, frozen or in a container with a rubber stopper (rubber is toxic to amniocytes) will be rejected. Clinical Information: The test determines fetal karyotype and allows prenatal detection of chromosomal rearrangements, aneuploidy, or mosaicism. Specimen Requirement: 30 mL amniotic fluid in clean container; Minimum 5 mL; Ambient; Discard first 2 mL of amniotic fluid. Collect specimen in two screw top plastic tubes. Do not centrifuge. *OR* 20 mL amniotic fluid in clean comtainer; Minimum 5 mL; Ambient; Early amniocentesis. Discard first 2 mL of amniotic fluid. Collect specimen in two screw top plastic tubes. Do not centrifuge. Reported: 10–14 days	11/8/22
Chromosome Analysis, Chorionic Villus	СVСΥТО	Includes:  Cells Counted Cells Analyzed Cells Karyotyped GTG Band Resolution Cytogenetic Diagnosis Cytogenetic Interpretation Specimen Type Director Review Special Information: Specimen is collected in syringe (transabdominal) or catheter (transcervical) and transferred by flushing with the media from the sterile container back into it. After collecting the specimen, wash with sterile saline solution (NaCl 0.95%) containing sodium heparin (two to three drops of sodium heparin in 10 mL of saline). Carefully transfer the specimen, into the CVS transport tube, using a sterile Pasteur pipette or a sterile fine needle forceps. Be sure to fill transport tubes completely with media. Samples from twin (multiple) pregnancies should be appropriately labeled and placed in separate transport containers with a separate request form for each twin. Do NOT freeze. Frozen specimens, specimens placed in fixative, improper labeling, and no villi submitted in specimen are unacceptable conditions.  Specimen Requirement: 30 mg chorionic villus in RPMI media; Minimum 5 mg; Ambient; Do NOT freeze or place in fixative. Deliver specimen to Cleveland Clinic Laboratories on the day of collection.  Reported: 7–11 days	11/8/22
Cryptococcus Ag Detection	CAD	CPT: 87327	effective immediately

Test Name	Order Code	Change	Effective Date
CYP2D6 (Cytochrome P450 2D6)	2D6GTP	Includes:  2D6GENO Specime CYP2D6 Genotype CYP2D6 Phenotype Interpretation  Special Information: Plasma, serum and frozen specimens in glass collection tubes will be rejected. Specimens collected in sodium heparin or lithium heparin are unacceptable. Whole blood is the preferred specimen type. Saliva samples that yield inadequate DNA quality and/or quantity will be reported as inconclusive if test performance does not meet laboratory-determined criteria for reporting. Saliva is only validated for the OpenArray and CNV portions of testing and not the long-range PCR/duplication testing. Long-range PCR/duplication testing will not be performed for saliva samples. If long-range PCR/duplication testing is performed, additional charges will apply and TAT will be extended by five to seven days. Approximately less than 5% of samples require 2D6 copy number determination. This test is New York DOH approved.  Reference Range:  2D6GENO SPECIMEN (2D6GS): Refer to report CYP2D6 GENOTYPE (CYP2DG): Refer to report CYP2D6 PHENOTYPE (PHE2D6): Refer to report	11/14/22
Cysticercus IgG Ab, CSF	CYSGCS	Stability: Ambient: After separation from cells: 48 hours Refrigerated: After separation from cells: 2 weeks Frozen: After separation from cells: 1 month (Avoid repeated freeze/thaw cycles)  Reference Range: < 9 U: Negative—No significant level of cysticercosis IgG antibody detected. 9–11 U: Equivocal—Recommend repeat testing in 2-4 weeks with fresh sample. > 11 U: Positive—IgG antibodies to cysticercosis detected, which may suggest current or past infection.	effective immediately
Cysticercus IgG Ab, Serum	CYSGBL	Stability: Ambient: After separation from cells: 48 hours Refrigerated: After separation from cells: 2 weeks Frozen: After separation from cells: 1 month (Avoid repeated freeze/thaw cycles)  Reference Range: < 9 U: Negative–No significant level of cysticercosis IgG antibody detected. 9–11 U: Equivocal–Recommend repeat testing in 2-4 weeks with fresh sample. > 11 U: Positive–IgG antibodies to cysticercosis detected, which may suggest current or past infection.	effective immediately
Fentanyl and Metabolite Confirmation, Urine	UFENT	<b>Test Name:</b> Previously Fentanyl and Metabolite, Urine <b>Clinical Information:</b> For Specimen Validity Interpretations, the following rules are applied: Diluted: Creatinine is greater than or equal to 2 mg/dL but less than 20 mg/dL and Specific Gravity is <b>less than 1.003.</b> Substituted: Creatinine is less than 2 mg/dL and the Specific gravity is less than <b>1.003</b> or greater than or equal to <b>1.020.</b> Adulterated: pH is less than 4 or greater than or equal to 11; Nitrite is greater than or equal to 500 mg/L; Chromate is greater than or equal to 50 mg/L; Oxidant is greater than or equal to 200 mg/L.	11/17/22
FISH Insight Analysis	ISIGHT	Includes: Cells Counted Cells Analyzed Cytogenetic Diagnosis Cytogenetic Interpretation Specimen Type Director Review Special Information: Do not centrifuge for any reason. It is standard of care that patients having InSight also have chromosome analysis performed to confirm InSight findings and to identify other abnormalities undetectable by InSight. Specimens which are frozen, low volume, hypocellular, submitted in fixative, glass containers or rubber stoppered tubes (rubber is toxic to amniocytes) will be rejected.  Specimen Requirement: 5 mL amniotic fluid in sterile container; Ambient Reported: 3–4 days	11/8/22

Test Name	Order Code	Change	Effective Date
FLT3 ITD and TKD Mutation Detection by PCR	FLT3IT	Includes: FLT3 Source ITD Result ITD Ratio TKD Result FLT3 ITD and TKD Mutation Detection Special Information: DNA isolation is performed Sunday–Saturday. Plasma, serum, FFPE tissue blocks/slides, or frozen tissue will be rejected. Specimens collected in anticoagulants other than EDTA or sodium heparin are unacceptable. Clotted or grossly hemolyzed specimens will be rejected. This test is New York DOH approved. Days Performed: Varies	11/14/22
Hepatitis B Surface Ab	AHBSAG	For interface clients only–Test build may need to be modified  Name: Previously Hepatitis B Surface Ab, Qual.  Clinical Information: To assess adequacy of recent or remote immune response to HBV infection or vaccination. Negative values: No evidence of antibodies to Hepatitis B surface antigen. Equivocal values: Indeterminate result. In patients who were vaccinated 6-8 weeks prior to this draw or previously infected with HBV, repeat testing is suggested. Those who were vaccinated for Hepatitis B virus years ago, may fall into this category due to waning immunity over time. Clinical correlation is required. Positive values: These results are consistent with immunity to the hepatitis B virus due to previous exposure to Hepatitis B virus or Hepatitis B vaccination.  Reference Range:  Hepatitis B Surface Ab, Qual. (AHBSAG): Negative  Hepatitis B Surface Ab, Quant (AHBSQ):  < 8.00 mIU/mL: Negative  8.00-11.99 mIU/mL: Equivocal  > or = to 12.00 mIU/mL: Positive	12/13/22
Lead, Blood	LEAD2	Clinical Limitation: Specimens received in BD lavender-top EDTA tubes will be reported with the following comment: Specimen received in a non-certified metal free container, which may produce a falsely elevated result. We recommend confirming elevated results utilizing a specimen collected in a certified metal free tube (royal blue top EDTA). Lavender-top Greiner Vacuette tubes with EDTA are not acceptable.  Specimen Requirement: 1 mL whole blood in EDTA (Royal blue) tube; Refrigerated *OR* 1 mL whole blood in EDTA (Lavender) tube; Refrigerated; Lavender-top BD Vacutainer tubes with EDTA are acceptable, but not recommended.	effective immediately
Orthopoxvirus (Includes monkeypox virus) by PCR	MONKEY	Test Name: Previously Monkeypox Virus Qualitative PCR Clinical Limitation: This test is intended for the detection of non-variola Orthopoxvirus DNA. A negative result does not rule out the presence of PCR inhibitors in the patient specimen or assay specific nucleic acid in concentrations below the level of detection by the assay. Clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status.  Clinical Information: This qualitative PCR test is used to detect members of the Orthopoxviruses, including monkeypox virus and vaccinia virus. This assay does not differentiate members of the Orthopoxviruses. Due to the 2022 global monkeypox outbreak, a detected result is most likely due to monkeypox virus. Identification of non-variola Orthopoxvirus DNA in an individual without suspicion for other recent Orthopoxvirus exposure meets the CDC definition for a "probable case" of monkeypox. Other Orthopoxviruses may be considered if appropriate.  Specimen Requirement: swab with lesion fluid in Universal Transport Media (UTM); Frozen; Specimen source required. *OR* swab with lesion fluid in Viral Transport Media; Frozen; Specimen source required.  Stability:  Ambient: 48 hours Refrigerated: 7 days Frozen: 30 days Reference Range: Not Detected Days Performed: Mon, Wed, Fri	12/13/22

Test Name	Order Code	Change	Effective Date
PML/RARA RTPCR	APLPCR	Includes: PML-RARA Translocation Source PML-RARA Translocation PML-RARA Translocation Quant Special Information: Blood, bone marrow; CRITICAL REFRIGERATED. Extracted RNA: CRITICAL FROZEN. RNA isolation performed Sun–Sat. The following specimens are unacceptable: Severely hemolyzed or clotted specimens, serum, plasma, CSF, ambient bone marrow or whole blood, frozen bone marrow or whole blood, extracted DNA, RNA extracted by a non-CLIA lab, bone core, FFPE tissue, specimens collected in anticoagulants other than EDTA. This test is New York DOH approved.	11/14/22
		Specimen Requirement: 5 mL whole blood in EDTA (Lavender) tube; Minimum 3 mL; Refrigerated; Critical refrigerated. Specimen must be delivered to Cleveland Clinic Laboratories by 3 p.m. EST on the day of collection. DO NOT collect the day before or the day of a major holiday. Separate specimens must be submitted when multiple tests are ordered. *OR* 3 mL bone marrow in EDTA (Lavender) tube; Minimum 1 mL; Refrigerated; Critical refrigerated. Specimen must be delivered to Cleveland Clinic Laboratories by 3 p.m. EST on the day of collection. DO NOT collect the day before or the day of a major holiday. Separate specimens must be submitted when multiple tests are ordered. *OR* Extracted RNA; Critical frozen. Transport 40 uL extracted RNA at a concentration of at least 40 ng/uL (minimum 40 uL) using a tissue transport kit (ARUP supply #47808). RNA must be extracted by a CLIA certified lab. Separate specimens must be submitted when multiple tests are ordered.  Stability:  Ambient: Unacceptable Refrigerated: Blood, bone marrow: 48 hours; Extracted RNA: Unacceptable Frozen: Blood, bone marrow: Unacceptable; Extracted RNA: Indefinitely	
Protein / Creatinine Ratio	PRATIO	For interface clients only–Test build may need to be modified  Clinical Information: Adult Proteinuria Categories: <0.15 mg/mg is considered normal to mildly increased 0.15 – 0.50 mg/mg is considered moderately increased >0.50 mg/mg is considered severely increased KDIGO. (2013). KDIGO 2012  Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease. Official Journal of the International Society of Nephrology, 3(1), 1-150.  Reference Range:  Protein / Creatinine Ratio (PCRAT): <0.15 mg/mg  Creatinine, Urine (UCRR): 20–300 mg/dL	effective immediately
Protein, Urine 24 Hour	UTP24	For interface clients only–Test build may need to be modified Clinical Information: Adult Proteinuria Categories: <0.15 g/24 hours is considered normal to mildly increased 0.15 – 0.50 g/24 hours is considered moderately increased >0.50 g/24 hours is considered severely increased KDIGO. (2013). KDIGO 2012 Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease. Official Journal of the International Society of Nephrology, 3(1), 1-150.  Reference Range: <0.15 g/24 hour	effective immediately

Test Name	Order Code	Change	Effective Date
Sertraline	SERTRA	Includes: Sertraline Serum or Plasma  Special Information: Specimen should be collected prior to next dose (trough)—at steady state concentration. Whole blood is unacceptable. Gel separator tubes, light blue (citrate) tubes, and SPS or ACD solution (yellow) tubes will be rejected. This test is New York DOH approved.  Clinical Information: Sertraline is a selective serotonin reuptake inhibitor antidepressant drug indicated for the treatment of major depressive disorder, obsessive-compulsive disorder, posttraumatic stress disorder, social anxiety disorder, and premenstrual dysphoric disorder. Sertraline doses range from 50-200 mg/day to produce serum concentration that range from 30-200 ng/mL. Dosing above 200 mg/day may increase the risk of adverse effects. Adverse effects may include dry mouth, headache, dizziness, fatigue, somnolence, tremor, nausea, and diarrhea. The risk of serotonin syndrome is increased with concomitant use of other serotonergic drugs. Concomitant use of sertraline with anticoagulants and nonsteroidal anti-inflammatory drugs may increase the risk of bleeding.  Stability:  Ambient: After separation from cells: 24 hours Refrigerated: After separation from cells: 2 weeks Frozen: After separation from cells: 4 months  Reference Range: Therapeutic range: 30–200 ng/mL Toxic: Greater than 300 ng/mL	11/14/22
Т3	T3	Special Information: Note: Biotin disclaimer has been removed.	11/15/22
T3, Free	FREET3	Special Information: Note: Biotin disclaimer has been removed.	11/15/22
T4	T4	Special Information: Note: Biotin disclaimer has been removed.	11/15/22
Trazodone	DESYRL	Includes: Trazodone Serum/Plasma  Special Information: Do not use gel separator tubes. Collect specimen prior to next dose (trough)—at steady state concentration. This test is New York DOH approved.  Clinical Information: Trazodone is a selective serotonin reuptake inhibitor antidepressant drug indicated for the treatment of major depressive disorder. The pharmacokinetics of trazodone is influenced by drug-drug interactions that induce or inhibit CYP3A4 metabolism. Adverse effects may include sedation, fatigue, headache, blurred vision, nausea and cardiac arrhythmia. The risk of serotonin syndrome is increased with concomitant use of other serotonergic drugs. Concomitant use of trazodone with anticoagulants and nonsteroidal anti-inflammatory drugs may increase the risk of bleeding.  Stability:  Ambient: After separation from cells: 24 hours Refrigerated: After separation from cells: 2 weeks Frozen: After separation from cells: 4 months  Reference Range: Therapeutic: 800–1600 ng/mL Toxic: Not well established  Days Performed: Wed  Reported: 2–9 days	11/14/22
Venlafaxine & Metabolite	VENLA	Special Information: Do not use serum separator tubes. Separate serum from cells within 2 hours of collection. This test is New York DOH approved.  Clinical Information: This test is useful for monitoring serum concentration during therapy, evaluating potential toxicity, and evaluating patient compliance. Draw blood immediately prior to next scheduled dose. Blood drawn from patients 12 hours after an oral dose is also appropriate. It is customary to treat the patient at bedtime with a dose, then collect specimen the following morning prior to next dose.  Stability:  Ambient: 28 days Refrigerated: 28 days Frozen: 28 days Reference Range: 100–400 ng/mL Reported: 2–5 days	effective immediately

#### New Tests

Test Name	Order Code	Change	Effective Date
Fentanyl Screen, Qualitative, Urine	UFENTS	Note: New test was announced in the October update, but financial information was not available at that time CPT: 80307 Price: \$85.00	11/17/22
FISH for CRLF2 and CRLF2/IGH Panel Blood	CRIGBP	Note: New test was announced in the September update, but financial information was not available at that time $ \textbf{CPT:} \ 88271x4; \ 88275x2; \ 88291x1; \ 88237x1 $ $ \textbf{Price:} \ \$915.00 $	effective immediately
FISH for CRLF2 and CRLF2/IGH Panel Bone Marrow	CRIGMP	Note: New test was announced in the September update, but financial information was not available at that time CPT: $88271x4$ ; $88275x2$ ; $88291x1$ ; $88237x1$ Price: $$915.00$	effective immediately
FISH for CRLF2/IGH Blood	CRIGHB	Note: New test was announced in the September update, but financial information was not available at that time CPT: 88271; 88275; 88291; 88237 Price: \$596.00	effective immediately
FISH for CRLF2/IGH Bone Marrow	CRIGHM	Note: New test was announced in the September update, but financial information was not available at that time $ \textbf{CPT:} \ 88271x2; \ 88275x1; \ 88291x1; \ 88237x1 $ $ \textbf{Price:} \ \$709.00 $	effective immediately

#### Fee Increases

Test Name	Order Code	List Fee	CPT Code	Effective Date
Gastric Parietal Cell IgG Serum	PARIES	\$99.00	83516	effective immediately
Histoplasma galactomannan Antigen, Urine	UHISTO	\$85.00	87385	effective immediately
Plasminogen Activator Inhibitor Antigen	PAI1M	\$400.00	85415	effective immediately

#### Fee Reductions

Test Name	Order Code	List Fee	CPT Code	Effective Date
pH Urine by pH Meter	PHU	\$24.00	83986	effective immediately

#### Discontinued Tests

Test Name	Order Code	Test Information	Effective Date
Adenovirus Culture	VADNO	Test will no longer be orderable. Recommended replacement test is Adenovirus PCR (ADEPCR).	12/13/22
Cytomegalovirus Rapid Culture	CMVCUL	Test will no longer be orderable. Recommended replacement tests are dependent on specimen type. CMV, qualitative by PCR, non-blood (CSF, bone marrow, amniotic fluid, ocular fluid) (CMVCSF) or Cytomegalovirus DNA Detection and Quantitation by PCR (CMVQNT) or New York Cytomegalovirus by Quantitative PCR (NYCMV) for New York patients.	12/13/22
Cytology, SurePath Liquid-Based Pap Test	SPPAP	Test will no longer be orderable.	12/13/22
Cytology, SurePath Liquid-Based Pap test and HPV, High Risk with 16 and 18 Genotype by PCR, SurePath (for routine co-testing in women over 30)	SPHPV	Test will no longer be orderable.	12/13/22
Enterovirus Culture	VENT	Test will no longer be orderable.	12/13/22
Cytology, SurePath Liquid-Based Pap Test with Reflex to human Papillomavirus (HPV), High Risk with 16 and 18 Genotype by PCR, SurePath	SPLBP	Test will no longer be orderable.	12/13/22
Hepatitis B Surface Ab, Immunity	AHBSI	Test will no longer be orderable. Recommended replacement test is Hepatitis B Surface Ab (AHBSAG)	12/13/22
Hepatitis B Surface Ab, Quant	AHBSQ	Test will no longer be orderable. Recommended replacement test is Hepatitis B Surface Ab (AHBSAG)	12/13/22
Human Papillomavirus (HPV) DNA Detection with Genotyping 16,18, High-Risk Types by PCR, Sure Path	HPVHRS	Test will no longer be orderable.	12/15/22
Humoral Immunity Panel I	HUMOR1	Test will no longer be orderable. Recommended replacement tests are Immunoglobulins (SERIMM), IgG Subclasses 1,2,3,4 (IG1234), Diphtheria/Tetanus Antibody (DIPTET), and Pneumococcal IgG Antibodies, 14 Serotypes (PNEUMG).	12/13/22
Humoral Immunity Panel II	HUMORA	Test will no longer be orderable. Recommended replacement tests are Diphtheria/ Tetanus Antibody (DIPTET), and Pneumococcal IgG Antibodies, 14 Serotypes (PNEUMG).	12/13/22
Leishmaniasis Antibody IFA	LEISH	Test will no longer be orderable.	12/13/22
Paroxetine	PAROX	Test will no longer be orderable.	effective immediately
Trypsin	TRYPSI	Test will no longer be orderable.	effective immediately